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EXAMINER
MILLER, MARINA I

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/975,853	AMDAHL, MICHAEL J.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☒ Claim(s) *6,14 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' submission filed on 1/23/2006 is acknowledged. Claims 1-16 are pending. Claims 1-16 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

Information Disclosure Statement

Information Disclosure Statements (IDS) filed 11/03/2003 has been considered in full.

Claim Objections

Claim 6 is objected to because of the following informalities: claim 6, as amended, recites "method of treating." Claim 6 is directed to an independent method of treating a disease and should recite "[a] method of treating." Appropriate correction is required.

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 14 recites the limitation "wherein the vitamin D therapy results in the prevention or treatment." Claim 14 depends from claim 13. Claim 13 is directed to a method of treating a patient using a regression model. The limitation of claim 14 constitutes an intended use of the method of claim 13 and does not further limit the method of claim 13.

Claim 15 is objected to because of the following informalities: claim 15 recites "[a] method of claim 8." Claim 15 depends from claim 8, and therefore should recite "[the] method of claim 8." Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12-14 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 12 recites a method of determining an initial dose of a vitamin D compound using a zero-intercept linear regression model. Claim 13 recites a method of treating a patient undergoing vitamin D therapy for ESRD wherein a zero-intercept regression model is used to determine an initial dose of a vitamin D compound. Claim 14 depends from claim 13 and further recites "wherein the vitamin D therapy results in the prevention or treatment." However, not all processes are statutory under 35 U.S.C. 101. *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility.* 1300 O.G. 4, on 22 November 2005 (published at the USPTO web site http://www.uspto.gov/web/patents'patog/week47/OG/TOC.htm). If claims are directed to abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature, "[i]n evaluating whether a claim meets the requirement of section 101, the claim must be considered as a whole to determine whether it is for a particular application of an abstract ideas, natural phenomena, or laws of nature." *Interim Guidelines for Examination of Patent Applications for*

Patent Subject Matter Eligibility, *Id.* section IV. C at 47-48 (the USPTO Web site's version). "To satisfy 101 requirements, the claim must be for a practical application … which can be identified … [i.e.] The claimed invention "transforms" an article or physical object to a different state or thing. [if not, then] The claimed invention otherwise produces a useful, concrete, and tangible result." *Id.* section IV. C. 2 at 48-49 (the USPTO Web site's version).

In the instant case, the claimed methods steps "describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic 'abstract idea.'" *Id.* section IV. B at 47 (the USPTO Web site's version). Specifically, the method of claim 12 recites only "using a zero-intercept linear regression model," *i.e.*, mathematical and/or statistical manipulations. While the preamble of claim 13 recites a method of treating a patient, claim 13 does not actually recite steps of treating and/or administering vitamin D and only recites "using" a zero-intercept regression model. Claim 14 further recites the vitamin D therapy results in the prevention or treatment of renal osteodystrophy or secondary hyperparathyroidism. However, claim 14 does not recite actual, positive steps of treating and/or preventing the diseases. Thus, the claimed methods do not transform or reduce an article or a physical object to a different stage or thing because the "result" of the methods (*i.e.*, using a zero-intercept linear regression model) is merely data (*e.g.*, dose or concentration of vitamin D) and is not equivalent to physical transformation. *Id.* section IV. C. 2 at 48-49. The claims do not recite tangible expression (*i.e.*, real-world result) of using a zero-intercept linear regression model, nor any recitation of an actual (*i.e.*, concrete) result in a form useful to one skilled in the art. Thus, the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory.

Lack of Utility

Claims 12-14 and 16 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claim 12 recites a method of determining an initial dose of a vitamin D compound using a zero-intercept linear regression model. Claim 13 recites a method of treating a patient undergoing vitamin D therapy using a zero-intercept regression model. The specification discloses that the claimed methods are useful for treating renal osteodystrophy, secondary hyperparathyroidism, and/or ESRD. However the disclosed utility is not applicable to the instant claims. Specifically, determining a dose of vitamin D and treating a patient have a substantial utility. However, the claimed methods do not result in determining a dose of vitamin D and treating a patient. The "result" of the claimed methods is using a zero-intercept linear regression model. Therefore, using a zero-intercept linear regression model would require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. Thus, claims 12-14 and 16 do not have substantial utility. Further, the specification does not disclose any specific utility for the invention because a zero-intercept linear regression model is applicable to a variety of methods. In order for the result of the method to be used for treating of a patient having renal osteodystrophy, secondary hyperparathyroidism, and/or ESRD, one skilled in the art must be aware of the correlation between the information received (result) (*i.e.,* using a zero-intercept linear regression model) and a condition to be treated. No such information is recited in the instant claims. Applicant is reminded that a "use" to perform further research is not a utility under 35 U.S.C. 101. For the reasons set forth above, the invention lacks a specific utility, and therefore lacks a patentable utility.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New rejections

Claim 1 recites "the initial dose" in line 1 of the preamble. There is insufficient antecedent basis for this limitation in the claim. Claim 1 does not recite "an initial dose" of a vitamin D compound. Claims 2-5 depend from claim 1. As the intended limitation is not clear, claims 1-5 are indefinite.

Claim 1 recites the limitation "final dose" in line 9 (step c). Claim 1 also recites earlier in the claim (line 5, step b) the limitation "a final dose" of a vitamin D compound. It is not clear whether "final dose" recited in line 9 is the same final dose recited in line 5 or some other final dose. As the intended limitation is not clear, claims 1-5 are indefinite.

Claim 6 recites the limitation "final dose" in line 8 (step c). Claim 6 also recites earlier in the claim (line 5, step b) the limitation "a final dose" of a vitamin D compound. It is not clear whether "final dose" recited in line 8 is the same final dose recited in line 5 or some other final dose. As the intended limitation is not clear, claim 6 is indefinite.

Claim 6 recites in line 9 the limitation "the initial dose." There is insufficient antecedent basis for this limitation in the claim. Claim 6 does not recite "an initial dose" of a vitamin D compound. As the intended limitation is not clear, claim 6 is indefinite.

Claim 7 recites in line 4 the limitation "the initial dose." There is insufficient antecedent basis for this limitation in the claim. Claim 7 does not recite "an initial dose" of a vitamin D compound. As the intended limitation is not clear, claims 7-9 and 15 are indefinite.

Claim 12 recites in line 1 the limitation "the initial dose." There is insufficient antecedent basis for this limitation in the claim. Claim 12 does not recite "an initial dose" of a vitamin D compound. As the intended limitation is not clear, claim 12 is indefinite.

Claim 12 recites a method of determining an initial dose of vitamin D using a zero-intercept linear regression model. The method recites a step of "using" and it is unclear what limitation of the method is intended because "using" a regression model does not achieve the goal of the method (*i.e.*, determining a dose of vitamin D). Thus, the relationship between the method step (*i.e.*, using) and the preamble is unclear. It is also not clear what method is intended because the claimed method does not recite actual, positive method steps. As the intended limitation is not clear, claim 12 is indefinite.

Claim 13 recites a method of treating a patient using a zero-intercept regression model. The method recites a step of "using" and it is unclear what limitation of the method is intended because "using" a regression model does not achieve the goal of the method (*i.e.*, treating a patient). Thus, the relationship between the method step (*i.e.*, using) and the preamble is unclear. It is also not clear what method is intended because the claimed method does not recite actual, positive method steps. As the intended limitation is not clear, claim 13 is indefinite.

Claim 14 recites the limitation "wherein the vitamin D therapy results in the prevention or treatment." Claim 14 depends from claim 13. It is not clear what further limitation of claim 13 is intended because the limitation of claim 14 does not further limit claim 13. It is also unclear

what limitation is intended because the method of claims 13-14 does not comprise active, positive steps of preventing and/or treating diseases. As the intended limitation is not clear, claim 14 is indefinite. It is noted that a method of "preventing" the recited diseases may not be enabled; however, as it is unclear what method is actually intended, the claims are rejected herein only for indefiniteness.

Claim 13 recites the limitations "the initial dose" and "the vitamin D compound." There is insufficient antecedent basis for this limitation in the claim. Claim 13 does not recite "an initial dose" and "a vitamin D compound." As the intended limitation is not clear, claim 13 is indefinite.

Claim 14 recites the limitations "the prevention." There is insufficient antecedent basis for this limitation in the claim. Claim 14 depends from claim 13. Claim 13 does not recite "preventing" diseases. As the intended limitation is not clear, claim 14 is indefinite.

Answer to the arguments

Claims 5 and 9-11 recite the limitation "bPTH/80." The claims were previously rejected in the Office action mailed 8/4/2003. Applicants argue that the limitation is clear and means a baseline PTH divided by 80, not a baseline PTH equals 80. Applicants' arguments have been considered, but are found not persuasive.

In response, it is noted that the limitation "bPTH/80" makes the claims vague and indefinite because it is unclear whether the limitation is intended to mean the initial dose of vitamin D equals the amount of bPTH divided by factor of 80; the initial dose equals the amount of some other PTH (called PTH/80); the initial dose equals a dose (or an initial dose) of the dose

of vitamin D for the hormone bPTH/80; *etc*. The examiner maintains that the limitation renders claims 5 and 9-11 indefinite, and the rejection is maintained for the reasons stated above and in the previous office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin, *Am. J. Kidney Diseases*, 32(4), Suppl. 2 (October 1998), pages S61-66.

Martin discloses treating patients with end-stage renal disease (ESRD) and secondary hyperparathyroidism comprising administering an initial dose of vitamin D to the patients (pages S61-62). Martin discloses a baseline PHT (p. S62, left col. and fig. 2, 4). Martin discloses a baseline PTH being 800 pg/ml (fig. 2), which is divisible by 80. Thus, Martin anticipates claims 10 and 11.

Claims 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Knutson, US 5,602,116.

Knutson discloses treating patients with end-stage renal disease (ESRD) and secondary hyperparathyroidism comprising administering an initial dose of vitamin D to the patients (col. 4, lines 45-59 and example 3). Knutson discloses a baseline PTH being 480, which is divisible by 80 (col. 11, line 9). Thus, Knutson anticipates claims 10-11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin, *Am. J. Kidney Diseases*, 32(4), Suppl. 2 (October 1998), pages S61-66, as applied to claims 10-11 above, in view of Riviere, US 6,066,091, and further in view of SAS Technical Support, GRAPH/GPLOT, 1990.

Martin discloses a method of treating ESRD and secondary hyperparathyroidism with vitamin D (p. S61). Martin discloses measuring a patient baseline PTH (p. S62) and determining a final dose of vitamin D, wherein the final dose is a dose associated with a stable reduction in PTH in response to the treatment (p. S62, left col.). Martin discloses a stepwise adjustment of the dose of vitamin D based on the PTH level and the final dose of vitamin D in order to prevent hypercalcemia (p. S61 and S62). Martin discloses administering the adjusted dose (p. S62). Martin discloses a baseline PHT (p. S62, left col. and fig. 2, 4). Martin discloses a baseline PTH being 800 pg/ml (fig. 2), which is divisible by 80. Marin discloses statistical analysis of the treatment data (p. S62). Martin further discloses vitamin D_2, specifically paricalcitol (p. S61). Martin discloses a dose at least 1 mcg (p. S62, left col.).

Martin does not disclose calculating an initial dose of vitamin D using a regression analysis, and specifically using a zero intercept linear model.

Riviere discloses using a regression analysis for extrapolating pharmacological data (col. 2). Riviere discloses extrapolating a withdrawal interval for an adjusted dose of a compound from a prior withdrawal interval for a corresponding prior dose (col. 2; col. 8-9; col. 10, lines 36-40; claims 1, 3, 7). Riviere discloses using slop-parameters and intercepts (zero-time intercepts) (col. 9, lines 10-19). Rivier discloses administering an adjusted dose that has a required withdrawal period determined by the regression analysis (col. 7, lines 1-12).

Riviere does not specifically disclose calculating an initial parameter using two variables, *e.g.*, intercept (predicted value when X is 0) and a variable parameter (X).

SAS Technical Support manual discloses using GRAPH/GPLOT for the extrapolation of data based on two variables.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method Martin to use a regression analysis for extrapolating an initial dose, such as taught by Riviere and SAS Technical Support manual, where the motivation would have been to decrease a number of studies and participants when a new compound and/or formulation are to be tested, as taught by Riviere, col. 1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
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MM

MARJORIE A. MORAN
PRIMARY EXAMINER
3/30/06